P CT

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Madison, NJ 07940

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S.N.09/674368

 # 6

OIPE
MAY 1 3 2002
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PATENT & TRADEMARK OFFICE

Wyeth

May 2, 2002

Mr. Robert Sparr, Esq.
U.S. Patent and Trademark Office
Washington, D.C. 20231

RECEIVED

2 5 JUN 2002

International Division

Re: U.S. Application No. ACY-33377-00
Serial No. 09/674368
Assignee: American Cyanamid Company
Inventors: Metcalf et al.
Title: Vaccines Containing Recombinant Pilin Against Neisseria Gonorrhoeae

Dear Mr. Sparr:

I am writing this letter, pursuant to our telephone conversation of April 24, 2002, to request you to make a determination as to whether, based on the facts set out below, the Patent Office (the "Office") would be willing to withdraw the holding of abandonment in the above-identified application and provide the Applicants with an extension of time to respond to the "Notification of Defective Response."

STATEMENT OF MATERIAL FACTS AND REASONS FOR GRANTING RELIEF

The above-identified application (U.S. serial No. 09/674368) was filed as a "National Stage" application under 35 U.S.C. §371 on October 27, 2000, from a PCT application, International Application Number PCT/US99/09486, filed on April 29, 1999, and claims priority from U.S. Provisional Application No. 60/083,405 filed April 29, 1998.

The application as filed contained a sequence listing both in a computer readable form and as a paper copy, which was generated using PatentIn Version 2.0.

BEST AVAILABLE COPY

Wyeth Pharmaceuticals
Wyeth Consumer Healthcare
Fort Dodge Animal Health

On June 11, 2001, the Office mailed a "Notification to Comply with Requirements for Patent Application Containing Nucleotide Sequences and/or Amino Acid Disclosures" (the "Notification"), wherein the Office stated that the "computer readable form that had been filed with this application has been found to be damaged and/or unreadable" and requested the Applicants to submit a substitute computer readable sequence listing as required under 37 C.F.R. §§ 1.821 – 1.825. Specifically, in the Raw Sequence Listing Error Report (the "Report") mailed with the Notification the following errors were identified:

(1)   The number/text at the end of each line wrapped down to the next line; and

(2)   The file was not saved in ASC II (DOS) text as required by the sequence rules. (*see* Exhibit 1).

The report further cautioned the Applicants not to use the "copy to disk" function of the PatentIn Version 2.0 as a "bug" in the software would cause a corrupted file resulting in missing mandatory numeric identifiers and responses.

On December 12, 2001, the Applicants filed a response to the "Notification" with a petition for extension of time and fees. Along with the response, the Applicants submitted a substitute computer readable form and a paper copy of the sequence listing wherein the Applicants corrected the errors that were identified in the Report, together with a statement as required under 37 C.F.R. §§ 1.825. In generating the computer readable form of the sequence listing, wherein the errors identified in the Report were corrected, the Applicants used PatentIn Version 3.0 and the "Sequence Checker" function of Version 3.0.

On March 18, 2002, the Office mailed a "Notification of Defective Response" and set a "time limit of one month from the date of this Notification or the Notice of Missing Requirements, whichever is longer." The only error identified in the Raw Sequence Listing Error Summary Report that was sent with the Notification of Defective Response was an error caused by a "bug" in PatentIn Version 2.0, which caused sections <220> through <223> to be missing from amino acid sequences 2 and 4. (*see* Exhibit 2). The Report in paragraph 6

further stated that, "[n]ormally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence," and that the only way to rectify this error is to "manually copy the relevant <220> <223> section to the subsequent amino acid sequence."

The Applicants respectfully submit that the Applicants followed the suggestions of the Office in generating a substitute computer readable form of the sequence listing in responding to the Notification of July 11, 2001. The Applicants submit that due to software incompatibility between PatentIn Version 2.0 and the Version 3.0, the software failed to automatically generate sections <220> through <223> in the amino acid sequences 2 and 4. Furthermore, since the March 18, 2002 suggestion to manually copy the relevant sections <220> through <223> from the nucleic acid sequence 1 and 3 into the amino acid sequences 2 and 4 was not made in the "Raw Sequence Listing Error Report" mailed with the "Notification" of July 11, 2001, the Applicants were unaware that the missing mandatory sections needed to be corrected.
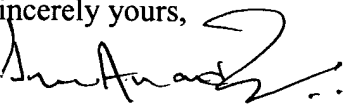
In view of the above, the Applicants respectfully request that the Office withdraw the holding of abandonment. The Applicants further request that the Applicants be granted an extension of time to file a response to the "Notification of Defective Response" together with a substitute computer readable form of the sequence listing.

CONCLUSION

In view of the material facts set forth above, the Applicants respectfully request that the holding of abandonment be withdrawn, and the Applicants be granted relief to submit a substitute corrected computer readable form of the sequence listing.

Should you need to contact me or need any additional information, please do not hesitate to call me at #(845) 602-2189.

Sincerely yours,
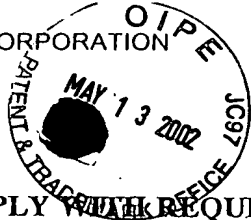
Anand (Andy) P. Iyer, Ph.D.

Alan M. Gordon
Reg. No. 30,637
Attorney for Applicants

AIP/awp

Wyeth

EXHIBIT A

I.A. FILING DATE	PRIORITY DATE

29 APR 99

DATE MAILED: 1 1 JUN 2001

NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant has submitted papers under 35 U.S.C. 371 to enter the national stage in the United States of America. The items indicated below, however, are missing. The period within which to correct the deficiency noted below and avoid abandonment is set forth in the accompanying Notification.

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):

☐ The application fails to comply with the requirements of 37 CFR 1.821-1.825.

☐ This application does not contain, a "Sequence Listing" as a separate part of the disclosure on paper copy or compact disc, as required by 37 CFR 1.821(c).

☐ A copy of the "Sequence Listing" in computer readable format has not been submitted as required by 37 CFR 1.821(e).

☐ A copy of the "Sequence Listing" in computer readable form has been submitted. The content of the computer readable form, however, does not comply with the requirements of 37 CFR 1.822 and/or 1.832, as indicated on the attached marked-up copy of the "Raw Sequence Listing."

☒ The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ The paper copy or compact disc of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).
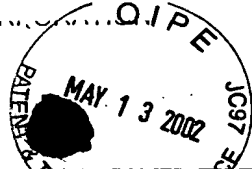
☐ Other: _____

APPLICANT MUST PROVIDE:

☒ An initial or substitute computer readable form (CRF) of the "Sequence Listing."

☐ An initial or substitute paper copy or compact disc of the "Sequence Listing," as well as an amendment directing its entry into the specification.

☒ A statement that the contents of the paper or compact disc and the computer readable form are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d).

FOR QUESTIONS REGARDING COMPLIANCE WITH THESE REQUIREMENTS, PLEASE CALL:

(703) 308-4216, for Rules interpretation,
(703) 308-4212, for CRF submission help,
(703) 287-0200, for PatentIn software help.

Deborah D. Williams

Telephone: 703-305-3744

ONE CAMPUS DRIVE
PARSIPPANY, NJ 07054

JC14 Rec'd PCT/PTO 13 MAY 2002
29 APR 99

1 JUN 2001
DATE MA

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

1. The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as ☐ a Designated Office (37 CFR 1.494) ☒ an Elected Office (37 CFR 1.495):

☒ U.S. Basic National Fee.　　　　　　　☐ Indication of Small Entity Status.
☒ Copy of the international application.　☒ Translation of the international application into English.
☒ Oath or Declaration of inventors(s).　☐ Translation of Article 19 amendments into English.
☐ Copy of Article 19 amendments.　　　☐ Other:
☐ Priority Document.
☒ The International Preliminary Examination Report in English and its Annexes, if any.
☐ Translation of Annexes to the International Preliminary Examination Report into English.

2. ☐ Applicant has requested early processing under 35 U.S.C. 371(f) but has not filed the following indicated items and/or the indicated items in paragraph 3 below. The Basic National Fee and the copy of the international application must be filed prior to 20 or 30 months from the priority date to avoid abandonment.
　　　☐ U.S. Basic National Fee.　　　　☐ Copy of the international application.

3. The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

　　☐ a. Translation of the application into English. A processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.
　　　　☐ The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.
　　☐ b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).
　　☐ c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), properly identifying the application (preferably by the International application number and international filing date). A surcharge will be required if submitted later than the appropriate 20 or 30 months from the priority date.
　　　　☐ The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.
　　☐ d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(e)).

4. Additional claim fees of $_____ as a ☐ large entity ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due (37 CFR 1.492(g)). See attached PTO-875.

5. ☒ Applicant has not submitted the required sequence listing pursuant to 37 CFR 1.821-1.825. See attached PCT/DO/EO/920.

ALL OF THE ITEMS SET FORTH IN 3(a)-3(d), 4 AND 5 ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 22 OR 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

6. If box 3a or 3c is checked, a translation of the Annexes MUST be submitted no later than the time period set above or the Annexes will be cancelled. A processing fee will be required if submitted later than 20 or 30 months from the priority date.
7. ☐ The Article 19 amendments are cancelled since a translation was not provided by the appropriate 20 (37 CFR 1.494(d)) or 30 (37 CFR 1.495(d)) months from the priority date.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

A copy of this notice MUST be returned with this response.

Enclosed: ☐ PCT/DO/EO/917　　　☐ Notice of Defective Translation
　　　　　☐ PTO-875　　　　　　☒ PCT/DO/EO/920

Deborah D. Williams

FORM PCT/DO/EO/905 (March 2001)　　　Telephone: 703-305-3744

I.A. FILING DATE	PRIORITY DATE
29 APR 9~	

DATE MAILED: **1 JUN 2001**

MAY 13 2002

8—11-0

6/14/0

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

1. The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as ☐ a Designated Office (37 CFR 1.494) ☒ an Elected Office (37 CFR 1.495):

☒ U.S. Basic National Fee.   ☐ Indication of Small Entity Status.

☒ Copy of the international application.   ☒ Translation of the international application into English.

☒ Oath or Declaration of inventors(s).   ☐ Translation of Article 19 amendments into English.

☐ Copy of Article 19 amendments.   ☐ Other:

☐ Priority Document.

☒ The International Preliminary Examination Report in English and its Annexes, if any.

☐ Translation of Annexes to the International Preliminary Examination Report into English.

2. ☐ Applicant has requested early processing under 35 U.S.C. 371(f) but has not filed the following indicated items and/or the indicated items in paragraph 3 below. The Basic National Fee and the copy of the international application must be filed prior to 20 or 30 months from the priority date to avoid abandonment.

☐ U.S. Basic National Fee.   ☐ Copy of the international application.

3. The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

☐ a. Translation of the application into English. A processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.

☐ The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.

☐ b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).

☐ c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), properly identifying the application (preferably by the International application number and international filing date). A surcharge will be required if submitted later than the appropriate 20 or 30 months from the priority date.

☐ The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.

☐ d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(e)).

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6. If box 3a or 3c is checked, a translation of the Annexes MUST be submitted no later than the time period set above or the Annexes will be cancelled. A processing fee will be required if submitted later than 20 or 30 months from the priority date.

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Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

A copy of this notice MUST be returned with this response.

Enclosed: ☐ PCT/DO/EO/917   ☐ Notice of Defective Translation
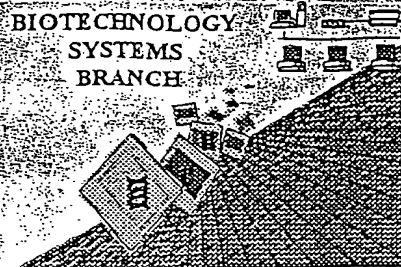
☐ PTO-875   ☒ PCT/DO/EO/920

Deborah D. Williams

Telephone: 703-305-3744

RECEIVED
JUN 13 2001
ANNETTE CROMER

FORM PCT/DO/EO/905 (March 2001)

RAW SEQUENCE LISTING ERROR REPORT

BIOTECHNOLOGY
SYSTEMS
BRANCH

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: _09/674,368_

Source: _PCT/09_

Date Processed by STIC: _3/09,2001_

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:
1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY
FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.
PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax)
PATENTIN 3.0 e-mail help: patin3help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 3.0 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW:

Checker Version 3.0

The Checker Version 3.0 application is a state-of-the-art Windows based software program employing a logical and intuitive user-interface to check whether a sequence listing is in compliance with format and content rules. Checker Version 3.0 works for sequence listings generated for the original version of 37 CFR §§1.821 – 1.825 effective October 1, 1990 (old rules) and the revised version (new rules) effective July 1, 1998 as well as World Intellectual Property Organization (WIPO) Standard ST.25.
Checker Version 3.0 replaces the previous DOS-based version of Checker, and is Y2K-compliant. Checker allows public users to check sequence listings in Computer Readable form (CRF) before submitting them to the United States Patent and Trademark Office (USPTO).
Use of Checker prior to filing the sequence listing is expected to result in fewer errored sequence listings, thus saving time and money.

Checker Version 3.0 can be down loaded from the USPTO website at the following address:
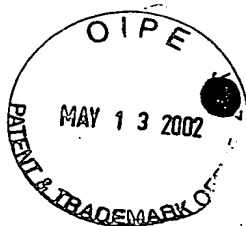
Raw Sequence Listing Error Summary

ERROR DETECTED	SUGGESTED CORRECTION	SERIAL NUMBER: 09/674,368

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

1 ___ Wrapped Nucleics
The number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".

2 ___ Wrapped Aminos
The amino acid number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".

3 ___ Incorrect Line Length
The rules require that a line not exceed 72 characters in length. This includes spaces.

4 ___ Misaligned Amino Acid Numbering
The numbering under each 5th amino acid is misaligned. This may be caused by the use of tabs
between the numbering. It is recommended to delete any tabs and use spacing between the numbers.

5 ___ Non-ASCII
This file was not saved in ASCII (DOS) text, as required by the Sequence Rules.
Please ensure your subsequent submission is saved in ASCII text so that it can be processed.

6 ___ Variable Length
Sequence(s) ___ contain n's or Xaa's which represented more than one residue.
As per the rules, each n or Xaa can only represent a single residue.
Please present the maximum number of each residue having variable length and
indicate in the (ix) feature section that some may be missing.

7 ___ PatentIn ver. 2.0 "bug"
A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid
sequence(s) _____. Normally, PatentIn would automatically generate this section from the
previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section
to the subsequent amino acid sequence. This applies primarily to the mandatory <220>-<223>
sections for Artificial or Unknown sequences.

8 ___ Skipped Sequences (OLD RULES)
Sequence(s) ___ missing. If intentional, please use the following format for each skipped sequence:
(2) INFORMATION FOR SEQ ID NO:X:
(i) SEQUENCE CHARACTERISTICS:(Do not insert any headings under "SEQUENCE CHARACTERISTICS")
(xi) SEQUENCE DESCRIPTION:SEQ ID NO:X:
This sequence is intentionally skipped

Please also adjust the "(iii) NUMBER OF SEQUENCES:" response to include the skipped sequence(s).

9 ___ Skipped Sequences (NEW RULES)
Sequence(s) ___ missing. If intentional, please use the following format for each skipped sequence.
<210> sequence id number
<400> sequence id number
000

10 ___ Use of n's or Xaa's (NEW RULES)
Use of n's and/or Xaa's have been detected in the Sequence Listing.
Use of <220> to <223> is MANDATORY if n's or Xaa's are present.
In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.

11 ___ Use of <213>Organism (NEW RULES)
Sequence(s) _____ are missing this mandatory field or its response.

12 ___ Use of <220>Feature (NEW RULES)
Sequence(s) ___ are missing the <220>Feature and associated headings.
Use of <220> to <223> is MANDATORY if <213>ORGANISM is "Artificial" or "Unknown"
Please explain source of genetic material in <220> to <223> section.
(See "Federal Register," 6/01/98, Vol. 63, No. 104, pp. 29631-32)   (Sec. 1.823 of new Rul

13 ___ PatentIn ver. 2.0 "bug"
Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted
file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing).
Instead, please use "File Manager" or any other means to copy file to floppy disk

PC:

RAW SEQUENCE LISTING   DATE: 03/07/2001
PATENT APPLICATION: US/09/674,368   TIME: 11:37:48

Input Set : A:\PTO.txt
Output Set: N:\CRF3\03072001\I674368.raw

Does Not Comply
Corrected Diskette Needed

```
   5 <110> APPLICANT: American Cyanamid Company
   7 <120> TITLE OF INVENTION: Vaccines Containing Recombinant Pilin Against Neisseria
   9        Gonorrhoeae or Neisseria Meningitidis
  11 <130> FILE REFERENCE: 33377-00/PCT
  13 <140> CURRENT APPLICATION NUMBER: US/09/674,368
  14 <141> CURRENT FILING DATE: 2000-10-27
  16 <160> NUMBER OF SEQ ID NOS: 24
  18 <170> SOFTWARE: PatentIn Ver. 2.0
```

OK see item 5 on Error Summary Sheet

ERRORED SEQUENCES

```
     299 <210> SEQ ID NO: 13
     300 <211> LENGTH: 31
     301 <212> TYPE: DNA
     303 <213> ORGANISM: Neisseria Meningitidis Class I
     305 <400> SEQUENCE: 13
E--> 306 ccggcgcgtc tctcacggcg aatggcccgg c                         31
     307                                     31
     396 <210> SEQ ID NO: 24
     397 <211> LENGTH: 22
     398 <212> TYPE: PRT
     399 <213> ORGANISM: Neisseria gonorrhoeae
     404 <400> SEQUENCE: 24
     405 Glu Ala Ile Leu Leu Ala Glu Gly Gln Lys Ser Ala Val Thr Glu Tyr
     406 1               5                   10                  15
     408 Tyr Leu Asn His Gly Lys
     410                 20
E--> 441 1
E--> 443 8
     445     ACY-33377-00
```

move up - format error (see item 1 on Error Summary Sheet)

delete at end of file

see following pages for more errors

Input Set : A:\PTO.txt
Output Set: N:\CRF3\03072001\I674368.raw

L:13 M:270 C: Current Application Number differs, Replaced Application Number
L:14 M:271 C: Current Filing Date differs, Replaced Current Filing Date
L:60 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
L:64 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
L:68 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
L:72 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
L:76 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
L:80 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
L:87 M:258 W: Mandatory Feature missing, <220> FEATURE:
L:87 M:258 W: Mandatory Feature missing, <223> OTHER INFORMATION:
L:194 M:258 W: Mandatory Feature missing, <220> FEATURE:
L:194 M:258 W: Mandatory Feature missing, <223> OTHER INFORMATION:
L:306 M:254 E: No. of Bases conflict, LENGTH:Input:0 Counted:31 SEQ:13
L:441 M:332 E: (32) Invalid/Missing Amino Acid Numbering, SEQ ID:24
M:332 Repeated in SeqNo=24

```
142    1              5              10              15
144  atc gcc atc gtc ggt atc ttg gca gcc gtc gcc ctg ccc gca tac caa    96
145  Ile Ala Ile Val Gly Ile Leu Ala Ala Val Ala Leu Pro Ala Tyr Gln
146          20              25              30
148  gac tac acc gcg cgc gcc caa atg tcc gaa gcc ctg act ttg gca gaa   144
149  Asp Tyr Thr Ala Arg Ala Gln Met Ser Glu Ala Leu Thr Leu Ala Glu
150          35              40              45
152  ggt caa aaa tcc gca gtg atc gag tat tat tcc gac aac ggc aca ttc   192
153  Gly Gln Lys Ser Ala Val Ile Glu Tyr Tyr Ser Asp Asn Gly Thr Phe
154          50              55              60
156  ccg aac agc aat act tcc gca ggt att gct gcc tct aac gag att aaa   240
157  Pro Asn Ser Asn Thr Ser Ala Gly Ile Ala Ala Ser Asn Glu Ile Lys
158  65              70              75              80
160  ggt aag tat gtg gca tcg gtt aag gtt gaa ggt aat gcc tct gtt gct   288
161  Gly Lys Tyr Val Ala Ser Val Lys Val Glu Gly Asn Ala Ser Val Ala
162              85              90              95
164  tct att acc gct acc atg aac tct agt aat gtg aat aag gac atc aaa   336
165  Ser Ile Thr Ala Thr Met Asn Ser Ser Asn Val Asn Lys Asp Ile Lys
166              100             105             110
169  ggt aaa acc ttg gta ctc gtc ggc aaa caa aac tcc ggt tcg gta aaa   384
170  Gly Lys Thr Leu Val Leu Val Gly Lys Gln Asn Ser Gly Ser Val Lys
171              115             120             125
173  tgg ttc tgc gga cag ccg gtt acg cgc gac aac gcc gac aac gac gac   432
174  Trp Phe Cys Gly Gln Pro Val Thr Arg Asp Asn Ala Asp Asn Asp Asp
175          130             135             140
177  gtc aaa gac gcc ggc aac aac ggc atc gaa acc aag cac ctg ccg tca   480
178  Val Lys Asp Ala Gly Asn Asn Gly Ile Glu Thr Lys His Leu Pro Ser
179  145             150             155             160
181  acc tgc cgc gat acg tca tct gat gcc aaa                           510
182  Thr Cys Arg Asp Thr Ser Ser Asp Ala Lys
183              165             170
186  <210> SEQ ID NO: 4
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196          20              25              30
198  Asp Tyr Thr Ala Arg Ala Gln Met Ser Glu Ala Leu Thr Leu Ala Glu
199          35              40              45
201  Gly Gln Lys Ser Ala Val Ile Glu Tyr Tyr Ser Asp Asn Gly Thr Phe
202          50              55              60
204  Pro Asn Ser Asn Thr Ser Ala Gly Ile Ala Ala Ser Asn Glu Ile Lys
205  65              70              75              80
207  Gly Lys Tyr Val Ala Ser Val Lys Val Glu Gly Asn Ala Ser Val Ala
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W--> 191
W--> 191

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 72 Ala Lys Thr Ala Asp Asn Ile Asn Thr Lys His Leu Pro Ser Thr Cys
 73 145                 150                 155                 160
 75 cgc gac gca agt gat gcc agc taa                                    504
 76 Arg Asp Ala Ser Asp Ala Ser
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 82 <213> ORGANISM: Artificial Sequence
 84 <220> FEATURE:
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 86   1               5                  10                  15
 88 Ile Ala Ile Val Gly Ile Leu Ala Ala Val Ala Leu Pro Ala Tyr Gln
 89             20                  25                  30
 92 Asp Tyr Thr Ala Arg Ala Gln Val Ser Glu Ala Ile Leu Leu Ala Glu
 93             35                  40                  45
 96 Gly Gln Lys Ser Ala Val Thr Glu Tyr Tyr Leu Asn His Gly Glu Trp
 97         50                  55                  60
100 Pro Gly Asn Asn Thr Ser Ala Gly Val Ala Ser Ser Ser Thr Ile Lys
101 65                  70                  75                  80
104 Gly Lys Tyr Val Lys Glu Val Thr Val Ala Asn Gly Val Ile Thr Ala
105             85                  90                  95
108 Thr Met Leu Ser Ser Gly Val Asn Lys Glu Ile Gln Gly Lys Lys Leu
109             100                 105                 110
112 Ser Leu Trp Ala Lys Arg Gln Asp Gly Ser Val Lys Trp Phe Cys Gly
113         115                 120                 125
115 Gln Pro Val Thr Arg Thr Asp Ala Lys Ala Asp Thr Val Ala Ala Ala
116         130                 135                 140
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131 <223> OTHER INFORMATION: Description of Artificial Sequence:Chimeric of
132       Neisseria Meningitidis Class II and Neisseria
133       Gonorrhoeae
135 <220> FEATURE:
136 <221> NAME/KEY: CDS
137 <222> LOCATION: (1)..(510)
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141 Met Glu Ala Ile Gln Lys Gly Phe Thr Leu Ile Glu Leu Met Ile Val
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EXHIBIT B

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box PCT
United States Patent and Trademark Office
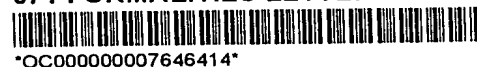Washington, D.C. 20231
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/674,368	Thomas N III Metcalf	33377-00

INTERNATIONAL APPLICATION NO.
PCT/US99/09486

I.A. FILING DATE	PRIORITY DATE
04/29/1999	

Alan M Gordon
Patent Law Department 2B
American Home Products Corporation
One Campus Drive
Parsippany, NJ 07054

CONFIRMATION NO. 6981
371 FORMALITIES LETTER

OC000000007646414

Date Mailed: 03/18/2002

NOTIFICATION OF DEFECTIVE RESPONSE

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- U.S. Basic National Fee
- Biochemical Sequence Diskette
- Biochemical Sequence Listing
- Copy of IPE Report
- Copy of references cited in ISR
- Copy of the International Application
- Copy of the International Search Report
- Oath or Declaration

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

Applicant is required to complete the response within a time limit of ONE MONTH from the date of this Notification or within the time remaining in the response set forth in the Notification of Missing Requirements, whichever is the longer. No extension of this time limit may be granted under 37 CFR 1.136, but the period for response set in the Notification of Missing Requirements may be extended under 37 CFR 1.136(a).

The following items **MUST** be furnished within the period set forth below:

- The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):

  - The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).
  - APPLICANT MUST PROVIDE:
    - An initial or substitute computer readable form (CRF) of the "Sequence Listing."

• For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (703) 308-4216
- To Purchase PatentIn Software, call (703) 306-2600
- For PatentIn Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

- The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice MUST be returned with the response.

DEBORAH D WILLIAMS

Telephone: (703) 305-3744

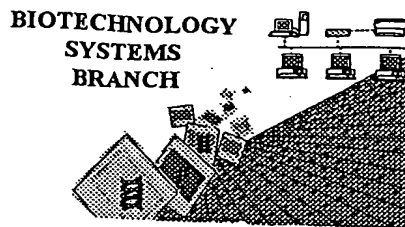PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
09/674,368	PCT/US99/09486	33377-00

FORM PCT/DO/EO/916 (371 Formalities Notice)

RAW SEQUENCE LISTING
ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 09/674,368 A

Source: PCT/09

Date Processed by STIC: 2/6/2002

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:
1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY
FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.
PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax)
PATENTIN 3.0 e-mail help: patin3help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE **CHECKER VERSION 3.1 PROGRAM**, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:
> http://www.uspto.gov/web/offices/pac/checker

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail. Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom. Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<http://www.uspto.gov/ebc/efs/downloads/documents.htm> , EFS Submission User Manual - ePAVE)
2. U.S. Postal Service: U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202
3. Hand Carry directly to:
   U.S. Patent and Trademark Office, Technology Center 1600, Reception Area, 7th Floor, Examiner Name, Sequence Information, Crystal Mall One, 1911 South Clark Street, Arlington, VA 22202
   Or
   U.S. Patent and Trademark Office, Box Sequence, Customer Window, Lobby, Room 1B03, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202
4. Federal Express, United Parcel Service, or other delivery service to: U.S. Patent and Trademark Office, Box Sequence, Room 1B03-Mailroom, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202

Revised 01/29/2002

Raw Sequence Listing Error Summary

RROR DETECTED	**SUGGESTED CORRECTION**	**SERIAL NUMBER:** _09/674,368A_

TTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

1___ Wrapped Nucleics
Wrapped Aminos
The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."

t___ Invalid Line Length
The rules require that a line not exceed 72 characters in length. This includes white spaces.

l___ Misaligned Amino Numbering
The numbering under each 5th amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.

l___ Non-ASCII
The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.

;___ Variable Length
Sequence(s)___ contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.

;___ PatentIn 2.0 "bug"
A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s) _2,4___. Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.

___ Skipped Sequences (OLD RULES)
Sequence(s) ___ missing. If intentional, please insert the following lines for each skipped sequence:
(2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
(i)   SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading)
(xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
This sequence is intentionally skipped

Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to include the skipped sequences.

___ Skipped Sequences (NEW RULES)
Sequence(s) ___ missing. If intentional, please insert the following lines for each skipped sequence.
<210> sequence id number
<400> sequence id number
000

___ Use of n's or Xaa's (NEW RULES)
Use of n's and/or Xaa's have been detected in the Sequence Listing.
Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present.
In <220> to <223> section, please explain location of n or Xaa; and which residue n or Xaa represents.

___ Invalid <213> Response
Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or is Artificial Sequence

___ Use of <220>
Sequence(s) ___ missing the <220> "Feature" and associated numeric identifiers and responses. Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section.
(See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32)   (Sec. 1.823 of Sequence Rules)

___ PatentIn 2.0 "bug"
Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.

___ Misuse of n
n can only be used to represent a single nucleotide in a nucleic acid sequence. N is not used to represent any value not specifically a nucleotide.

AMC/MH – Biotechnology Systems Branch – 08/21/2001

PCT09

RAW SEQUENCE LISTING   DATE: 02/06/2002
PATENT APPLICATION: US/09/674,368A   TIME: 14:15:57

Input Set : A:\33377PCT.APP.txt
Output Set: N:\CRF3\02062002\I674368A.raw

Does Not Comply
Corrected Diskette Needed

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 5 <110> APPLICANT: American Cyanamid Company
 7 <120> TITLE OF INVENTION: Vaccines Containing Recombinant Pilin Against Neisseria
 9       Gonorrhoeae or Neisseria Meningitidis
11 <130> FILE REFERENCE: 33377-00/PCT
13 <140> CURRENT APPLICATION NUMBER: US/09/674,368A
14 <141> CURRENT FILING DATE: 2001-12-11
16 <160> NUMBER OF SEQ ID NOS: 24
18 <170> SOFTWARE: PatentIn Ver. 2.0
20 <210> SEQ ID NO: 1
21 <211> LENGTH: 504
22 <212> TYPE: DNA
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25 <220> FEATURE:
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27       Neisseria Meningitidis Class I and Neisseria
28       Gonorrhoeae
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42              20                  25                  30
44 gac tac acc gcc cgc gcg caa gtt tcc gaa gcc atc ctt ttg gcc gaa 144
45 Asp Tyr Thr Ala Arg Ala Gln Val Ser Glu Ala Ile Leu Leu Ala Glu
46          35                  40                  45
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54  65                  70                  75                  80
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59 Gly Lys Tyr Val Lys Glu Val Thr Val Ala Asn Gly Val Ile Thr Ala
60      85                  85      90      90      95      95
62 aca atg ctt tca agc ggc gta aac aaa gaa atc caa ggc aaa aaa ctc 336
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64              100                 105                 110
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67 Ser Leu Trp Ala Lys Arg Gln Asp Gly Ser Val Lys Trp Phe Cys Gly
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← fr numbering

RAW SEQUENCE LISTING
PATENT APPLICATION: US/09/674,368A

DATE: 02/06/2002
TIME: 14:15:57

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Output Set: N:\CRF3\02062002\I674368A.raw

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   75 Ala Lys Thr Ala Asp Asn Ile Asn Thr Lys His Leu Pro Ser Thr Cys
-> 76 145                  150                  155                  160
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-> 87 <223> OTHER INFORMATION:
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   92               20                  25                  30
   95 Asp Tyr Thr Ala Arg Ala Gln Val Ser Glu Ala Ile Leu Leu Ala Glu
   96           35                  40                  45
   99 Gly Gln Lys Ser Ala Val Thr Glu Tyr Tyr Leu Asn His Gly Glu Trp
  100       50                  55                  60
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  104   65                  70                  75                  80
  107 Gly Lys Tyr Val Lys Glu Val Thr Val Ala Asn Gly Val Ile Thr Ala
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  111 Thr Met Leu Ser Ser Gly Val Asn Lys Glu Ile Gln Gly Lys Lys Leu
  112               100                 105                 110
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  116           115                 120                 125
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  135        Neisseria Meningitidis Class II and Neisseria
  136        Gonorrhoeae
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  139 <221> NAME/KEY: CDS
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RAW SEQUENCE LISTING   DATE: 02/06/2002
PATENT APPLICATION: US/09/674,368A   TIME: 14:15:57

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148 Ile Ala Ile Val Gly Ile Leu Ala Ala Val Ala Leu Pro Ala Tyr Gln
149             20                  25                  30
151 gac tac acc gcg cgc gcc caa atg tcc gaa gcc ctg act ttg gca gaa   144
152 Asp Tyr Thr Ala Arg Ala Gln Met Ser Glu Ala Leu Thr Leu Ala Glu
153             35                  40                  45
155 ggt caa aaa tcc gca gtg atc gag tat tat tcc gac aac ggc aca ttc   192
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157       50                  55                  60
159 ccg aac agc aat act tcc gca ggt att gct gcc tct aac gag att aaa   240
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161   65                  70                  75                  80
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165             85                  90                  95
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169             100                 105                 110
172 ggt aaa acc ttg gta ctc gtc ggc aaa caa aac tcc ggt tcg gta aaa   384
173 Gly Lys Thr Leu Val Leu Val Gly Lys Gln Asn Ser Gly Ser Val Lys
174          115                 120                 125
176 tgg ttc tgc gga cag ccg gtt acg cgc gac aac gcc gac aac gac gac   432
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178       130                 135                 140
180 gtc aaa gac gcc ggc aac aac ggc atc gaa acc aag cac ctg ccg tca   480
181 Val Lys Asp Ala Gly Asn Asn Gly Ile Glu Thr Lys His Leu Pro Ser
182 145                 150                 155                 160
184 acc tgc cgc gat acg tca tct gat gcc aaa                           510
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199             20                  25                  30
201 Asp Tyr Thr Ala Arg Ala Gln Met Ser Glu Ala Leu Thr Leu Ala Glu
202             35                  40                  45
204 Gly Gln Lys Ser Ala Val Ile Glu Tyr Tyr Ser Asp Asn Gly Thr Phe
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item 6

RAW SEQUENCE LISTING   DATE: 02/06/2002
PATENT APPLICATION: US/09/674,368A   TIME: 14:15:57

Input Set : A:\33377PCT.APP.txt
Output Set: N:\CRF3\02062002\I674368A.raw

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214            100                     105                 110
216 Gly Lys Thr Leu Val Leu Val Gly Lys Gln Asn Ser Gly Ser Val Lys
217         115                     120                 125
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Output Set: N:\CRF3\02062002\I674368A.raw

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338 gcataattcg tgtcgctcaa ggcgc                                  25
343 <210> SEQ ID NO: 18
344 <211> LENGTH: 39
345 <212> TYPE: DNA
346 <213> ORGANISM: Neisseria Meningitidis Class I
348 <400> SEQUENCE: 18
```

VERIFICATION SUMMARY   DATE: 02/06/2002
PATENT APPLICATION: US/09/674,368A   TIME: 14:15:59

Input Set : A:\33377PCT.APP.txt
Output Set: N:\CRF3\02062002\I674368A.raw

```
13 M:270 C: Current Application Number differs, Replaced Application Number
14 M:271 C: Current Filing Date differs, Replaced Current Filing Date
60 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
64 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
68 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
72 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
76 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
80 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:1
87 M:258 W: Mandatory Feature missing, <220> FEATURE:
87 M:258 W: Mandatory Feature missing, <223> OTHER INFORMATION:
194 M:258 W: Mandatory Feature missing, <220> FEATURE:
194 M:258 W: Mandatory Feature missing, <223> OTHER INFORMATION:
```